Appln No.: 09/913,325
Amendment Dated: October 26, 2005
Reply to Office Action of July 28, 2005

REMARKS/ARGUMENTS

This is in response to the Office Action mailed July 28, 2005 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claims 18-23 have been canceled, without prejudice, in light of the presence of claims of similar scope in pending US Patent Application 09/967,726.

Claims 6 and 18 remain rejected under 35 USC § 112, first paragraph, based upon an asserted lack of written description. The Examiner has likened the claims of the present application to those in *Rochester v Searle*, to the extent the claims antisense as the active agent. Applicants respectfully submit that this type of parsing of the issue is inappropriate. In *Rochester v. Searle*, no compound capable of achieving the stated function (inhibition of Cox-2) was disclosed. Thus, the inventors there had provided knowledge of a pathway whose inhibition might be significant, but no enablement and no written description of how to bring about the inhibition. The present case is different.

Applicants have discovered that limiting the expression of TRPM-2 has therapeutic benefits as reflected in the present claims. Unlike the patentee in *Rochester* they have embodied this discovery into an invention by providing compounds capable of achieving the result and showing the benefits of the result.

The Examiner's argument with respect to written description would have the effect of limiting an inventor to the specific compounds or type of compounds that they had worked with, even though it apparent to the inventor and everyone else that their contribution to the art is far broader than this, because they discovered a reason to do something. Thus, the Examiner's application of the written description requirement would either delay disclosure so that other types of therapeutic agents could be obtained and tested, or facilitate others in stealing the fruits of the inventors work because of the extra limitations in the claims. The Examiner has not offered any reasons grounded in case law or public policy why either of these results would be considered desirable. Thus, Applicants submit that the written description requirement with respect to claims 6 and 8 should be withdrawn.

The Examiner rejected claims 1, 3, 6-9, 12-15, 24, 26, 29 and 30 for obviousness-type double patenting in view of claims 2-6, 10 and 11 of US Patent No. 6,900,187. The '187 patent relates to a species of modified antisense oligonucleotide. As the Examiner has indicated, claims of the present application could be characterized as generic with respect to the issued claims of the '187 patent. This is not, however, all that is required for obviousness type double patenting.

First of all, it should be remembered that obviousness-type double patenting is fundamentally an equitable doctrine that was created by the courts to remedy a perceived unfair advantage to applicants with a string of inventions, and a resulting disadvantage to the public. In the present case, however, the PCT application corresponding to the present application, which the specific sequence of the claims of the '187 patent but not the specific modifications, was considered as prior art by the Examiner. Nevertheless, the claims of the '187 were found to be patentable, and granted on a first action allowance. The Examiner is therefore precluded from arguing that the claims of the '187 patent are an obvious variation of the present genus. Furthermore, the application of a double-patenting rejection in this case is improper because it places applicants in a worse position than a third party, he could not file a terminal disclaimer, but would still be able have bene able to obtain the '187 patent. Thus, an obviousness-type patenting rejection is inequitable and improper.

The Examiner also argues that a two-way test is not proper because there is no showing that administrative delay on the part of the patent office resulting in the later filed application being issued first. Applicants respectfully submit, however, that administrative delay by the patent office is not the sole test for determining applicability of the two way test. As stated in *In re Berg*, 46 USPQ2d 1226, 1229 (Fed Cir. 1998) the two way test is intended to address "[t]he essential concern ... to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, **through no fault of the applicants**, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." The order of issuance here was determined by the speed of prosecution in the PTO and not by applicants. Thus, even if the disclosure of the parent case were not prior art, the application of a two way test would be proper, and thus there should be no rejection.

For these reasons, Applicants again submit that the obviousness-type double patenting rejection should be withdrawn.

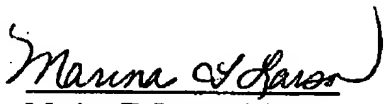
The Examiner has maintained the rejection of claims 1, 2, 4, 24, 25 and 27 as anticipated by or obvious over Sensibar et al. Applicants again traverse this rejection.

The Examiner argues that the experiments of Sensibar et al. "would have the effect of delaying progression of prostatic tumors from an androgen-independent state" and that the rejected claims are therefore anticipated or obvious." Applicants respectfully submit that several factors are relevant in this case. To the extent that any delay in progression did take place in the Sensibar experiments, it would have been de minimus because of the time frame involved. As noted in the specification of this application, the progression to androgen independence takes place over a period of many days. (see Fig. 1) In the tests of Sensibar, there is no indication that the tests lasted for any comparable period of this period of time, and thus no observation or

mention of any such delay. Thus, the Examiner's argument is one of "accidental anticipation." Accidental anticipation, however, where the result or occurrence that is of relevance to the invention was not appreciated is not anticipation at all. In this regard, *In re Marshall*, 198 USPQ 344 (CCPA 1978), if relevant. In *Marshall*, the invention dealt with the new pharmaceutical use (weight loss) for a previously known drug which was described in the PDR. The CCPA reversed the holding of anticipation observing that "If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accident or unwitting anticipation of an invention cannot constitute an anticipation." The same is applicable here. If any of the cells in Sensibar's cultures experienced a delay in progression to androgen independence it was an unrecognized accident, which cannot serve as an anticipation.

For the foregoing reasons, Applicants submit that this application is now in form for allowance. Favorable reconsideration and allowance are respectfully urged.

Respectfully submitted,



Marina T. Larson Ph.D.
PTO Reg. No. 32,038
Attorney for Applicant
(970) 468-6600